Exhibit F

KIRKLAND & ELLIS LLP
AND AFFILIATED PARTNERSHIPS

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June 27, 2006

VIA FACSIMILE & E-MAIL

Kurt Calia, Esq.
Covington & Burling
1201 Pennsylvania Avenue, N.W.
Washington, DC 20004-2401

Re: *In re '318 Patent Litigation*, Civil Action No. 05-356 (KAJ)

Dear Kurt:

This follows up on our previous correspondence and discussions concerning Janssen's refusal to provide additional dates for the 30(b)(6) deposition topics that it offered for June 23, 2006. As we discussed, Teva was not available on June 23. Janssen has subsequently refused to provide Teva with additional dates. For the reasons stated herein, as well as for those that we have discussed previously, we again ask that Janssen provide us with dates for Teva to depose Janssen's designee. Otherwise, we will raise this issue with the Court at the July 10 discovery hearing.

The 30(b)(6) deposition topics at issue were contained in Teva's First Notice of 30(b)(6) deposition as well as Teva's Second 30(b)(6) deposition notice. Teva noticed its Second 30(b)(6) deposition to take place on June 13, 2006. Plaintiffs' objections to that deposition stated, among other things, that "Plaintiffs' counsel are not available on that date," and Plaintiffs promised to "propose alternative dates and work out mutually agreeable timing with Teva." Yet plaintiffs only proposed one date – June 23 – which I informed you was a date on which Teva was not available. Plaintiffs have refused to propose any other alternative dates and to "work out mutually agreeable timing with Teva." This is not only improper, but in sharp contrast to the repeated accommodations made for plaintiffs' counsel including offering 4 different dates for Ms. Payne's deposition to accommodate plaintiffs, and even accepting a later date for the Court hearing on July 10 because plaintiffs' counsel was unavailable for the earlier one. In addition, you should note that scheduling depositions in this case must also be done to reasonably ensure the other defendants can attend and participate to the extent they wish to do so.

In addition, Teva's unavailability on June 23 was exacerbated by Janssen's production of over ***2,400*** pages of documents on June 20. Janssen's late production would have required Teva to review these documents just two days in advance of proposed June 23 deposition. – for which Janssen had not even identified the topics until June 19 in the first place. Janssen's insistence that Teva had to prepare for this 30(b)(6) deposition on such an unrealistic timetable is not

reasonable. Teva is entitled to adequate time to review and consider the production in advance of the 30(b)(6) depositions, and to prepare for the deposition on the specified topics.

In this regard, [redacted]. To the extent you have an explanation for why you believe Teva should have taken a deposition last week when you produced the relevant documents the week after, please provide it.

Further, you have stated that Janssen's Rule 30(b)(6) designee, Mr. Truyens, was not available on any date before the discovery deadline other than June 23 and that, as a result, if Teva was not able to take the deposition on that date, you would not propose alternative dates. First, I note that Teva has not noticed Mr. Truyens' deposition in his individual capacity; this is a 30(b)(6) deposition, and if Mr. Truyens is not available, then Janssen should designate another representative.

Second, as I have informed you, Teva is willing to take this deposition in July on a mutually-convenient date. The fact that such a deposition would occur after the June 30 fact discovery cutoff should not get in the way of such an arrangement. Indeed, Janssen has been willing to disregard the discovery cutoff when it comes to its own discovery -- you have made arrangements to take an Alphapharm 30(b)(6) deposition on ***July 6***. (K. Calia 6/14/06 email to A. Bernstein). Indeed, you have reserved the right to take the deposition of yet another Alphapharm employee ***after July 6*** if you are not satisfied with the testimony obtained on July 6. This accommodation was made by agreement between the parties ***without the "need to move the Court for an extension."*** (K. Calia 6/16/06 email to A. Kay) It is clear that your refusal to provide an alternate date for the June 23, 2006 has nothing to do with a good faith belief that such an arrangement would violate the Court's order. Just as is the case with Janssen's deposition of Alphapharm, the parties should agree to schedule Teva's deposition of Janssen without burdening the Court with this matter.

We remain willing to work with Janssen to reach an agreement with respect to a mutually agreed upon date for deposition testimony on the topics for which you have designated Mr. Truyens. If, however, Janssen continues to refuse to provide a date, we will seek relief from the Court at the scheduled July 10, 2006 hearing. We look forward to your response.

Sincerely,

Karen M. Robinson

cc: Steve Balick (via electronic mail)
John Shaw (via electronic mail)

Exhibit G

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE: '318 PATENT INFRINGEMENT LITIGATION	)))	C.A. No. 05-356-KAJ (consolidated)

PLAINTIFFS JANSSEN PHARMACEUTICA N.V.'S, JANSSEN, L.P.'S, AND SYNAPTECH, INC.'S OBJECTIONS AND RESPONSE TO DEFENDANTS TEVA PHARMACEUTICALS, USA, INC.'S AND TEVA PHARMACEUTICAL INDUSTRIES LTD'S SECOND SET OF INTERROGATORIES

Pursuant to Federal Rule 33 of Civil Procedure and the Local Civil Rules of this Court, Plaintiffs Janssen Pharmaceutica N.V., Janssen L.P., and Synaptech, Inc., (collectively, "Plaintiffs") hereby object and respond to Defendants Teva Pharmaceuticals, USA, Inc.'s and Teva Pharmaceutical Industries Ltd's (collectively, "Defendants" or "Teva") Second Set of Interrogatories (the "interrogatories"). Plaintiffs' response to these interrogatories is without prejudice to, and does not constitute a waiver of, Plaintiffs' rights to rely on other documents or information at trial. Plaintiffs also reserve the right under Rule 26(e) to supplement this response.

General Objections

A. Plaintiffs object to each of Defendants' interrogatories to the extent it seeks information that is (i) subject to the attorney-client privilege; (ii) subject to attorney work product immunity; and/or (iii) subject to any other privilege. Plaintiffs hereby claim such privileges and immunities to the extent implicated by each interrogatory, and exclude privileged and protected information from their responses. Any disclosure of such privileged or immunized information is inadvertent and is not intended to waive those privileges and immunities.

B. Plaintiffs object to the interrogatories on the grounds and to the extent that they call for the provision of information that is overbroad, unduly burdensome, and not relevant to the subject matter of the pending action or that is not reasonably calculated to lead to the discovery of admissible evidence.

C. Plaintiffs object to the interrogatories, and to the Definitions and Instructions therein, on the grounds and to the extent that they purport to impose any obligation on Plaintiffs that is beyond the scope of Rules 26 and 33 of the Federal Rules of Civil Procedure or other applicable law.

D. Plaintiffs' written responses and production of documents are based on information presently available to and located by Plaintiffs and their attorneys. As Plaintiffs have not completed their investigation of the facts relating to this case, their discovery in this action, or their preparation for trial, Plaintiffs' written responses and production of documents are made without prejudice to their right to supplement or amend their written responses and production of documents and to present evidence discovered hereafter at trial.

E. Plaintiffs object to the interrogatories to the extent that they purport to require disclosure or production of information subject to confidentiality requirements or expectations between Plaintiffs and any third party.

F. Plaintiffs' responses are provided without prejudice to Plaintiffs' right to oppose the admissibility or use of any document produced by Plaintiffs or any other party or third party in this case. Plaintiffs' production of a document in response to these interrogatories should not be taken as an admission concerning its authenticity, relevance, or admissibility. Further, any statement in these responses that Plaintiffs will produce

any non-privileged responsive documents that are discovered in a reasonable search of files within their possession, custody, or control should not be construed as an assertion that any such documents in fact exist; such a statement means only that Plaintiffs will conduct a reasonable, good-faith search for any such documents and will produce any non-privileged responsive documents that are found.

Plaintiffs reserve their right to require the return of any privileged document that may inadvertently be produced in response to these interrogatories. Plaintiffs also reserve the right to designate (or re-designate) any confidential document that may inadvertently be produced without the appropriate confidentiality designation.

G. Plaintiffs' objections and responses to the interrogatories, including any production of related documents, are not intended to waive or prejudice any objections Plaintiffs may assert now or in the future, including, without limitation, objections as to the relevance of the subject matter of any interrogatory or document request, or to the admissibility of any response or document or category of responses or documents at trial. Plaintiffs expressly reserve any and all rights and privileges under the Federal Rules of Civil Procedure, the Federal Rules of Evidence and any other law or rule, and the failure to assert such rights and privileges or the inadvertent disclosure by Plaintiffs of information protected by such rights or privileges shall not constitute a waiver thereof, either with respect to these responses or with respect to any future discovery responses or objections.

H. Plaintiffs object to the interrogatories to the extent that the burden or expense of the proposed discovery outweighs its likely benefit, taking into account the

needs of the case, the parties' resources, the importance of the issues at stake in the litigation, and the importance of the proposed discovery in resolving the issues.

I. Plaintiffs object to Defendants' definition of "you," "your," "Janssen," "Janssen Pharmaceutica N.V.," "Janssen, L.P.," and "Synaptech" as confusing, overly broad, and unduly burdensome. For purposes of these interrogatories, "you" and "your" shall refer to Janssen Pharmaceutica N.V., Janssen, L.P., and Synaptech, Inc., named Plaintiffs to this litigation. "Janssen" shall refer to the named Plaintiffs, Janssen Pharmaceutica, N.V. or Janssen, L.P., either collectively or individually, as specified in each of Plaintiffs' responses. Synaptech shall refer to Synaptech, Inc.

J. Plaintiffs object to these interrogatories to the extent they call for the collective knowledge and collective answer of separate entities.

K. Plaintiffs object to the interrogatories to the extent that they seek to impose an obligation on Plaintiffs to locate, obtain, and produce documents and things that are in the public domain, and therefore, are equally accessible to Defendants.

Specific Objections and Responses

Interrogatory No. 10

State the basis for Plaintiffs' disagreement, if any, with the positions set forth in Defendants' first supplemental response to Plaintiffs' Interrogatory No. 2, including without limitation the identity of all witnesses and Documents on which Plaintiffs rely as a basis for their disagreement.

Response:

In addition to the foregoing General Objections, Plaintiffs object that the interrogatory prematurely calls for information within the scope of expert discovery, and Plaintiffs reserve their rights to supplement and enlarge their positions and contentions concerning the subject matter of this interrogatory in the course of expert disclosure and testimony. Plaintiffs also object that discovery is ongoing, Defendants have refused to date to produce a witness in response to Plaintiffs' notice of deposition under Rule 30(b)(6) concerning Defendants' invalidity contentions, and Defendants' "first supplemental response to Plaintiffs' Interrogatory No. 2" was recently superseded by Defendants' Second Supplemental Response to Interrogatory No. 2, which was served on Plaintiffs on May 10, 2006. With respect to the identity of witnesses and documents, Plaintiffs refer Defendants to Plaintiffs' disclosures under Rule 26(a), which Plaintiffs reserve the right to supplement or amend.

Without waiving the foregoing objections, Plaintiffs disagree with the contentions set forth in Defendants' first and second supplemental responses to Plaintiffs' Interrogatory No. 2 and state that those contentions fail to support Defendants' asserted defense that Claims 1 and 4 of the '318 patent are invalid.

With regard to Defendants' asserted section 102(b) defense, the sole purported reference cited by Defendants in support of that defense – P.A. Bhasker, *Medical Management of Dementia*, THE ANTISEPTIC, 71(1):45-47 (1974) ("Bhasker") – does not constitute a written description of the invention claimed in Claims 1 and 4 of the '318 patent. Bhasker does not describe the use of galantamine to treat Alzheimer's disease, let alone dosage forms or amounts for such treatment, and to the contrary

describes progressive dementias as untreatable. The text of Bhasker thus teaches away from the invention claimed in Claims 1 and 4 of the '318 patent. (It is also noteworthy that the vast majority of the Defendants' paragraph IV notices concerning their allegations of invalidity did not even assert section 102 as a defense.) In addition, Defendants' responses fail to demonstrate that Bhasker was sufficiently accessible to the public interested in the art relevant to Claims 1 and 4 of the '318 patent, and Plaintiffs are unaware of Bhasker either being cited in any relevant literature or indexed in any relevant way prior to the filing of the application leading to the '318 patent.

With regard to Defendants' asserted section 103 defense, Defendants' response fails to support Defendants' contention that Claims 1 and 4 of the '318 patent are invalid for obviousness. Defendants' response fails to demonstrate either a motivation to combine references or a reasonable expectation of success from doing so. Defendants' response asserts that "these prior art articles teach the use of acetylcholinesterase inhibitors – a class of drugs that includes physostigmine and galantamine – and physostigmine specifically to treat Alzheimer's disease." However, the prior art teaches no such thing. To the contrary, there was considerable skepticism in the art about pharmacologic approaches to treatment of Alzheimer's generally, and about cholinesterase inhibitors specifically, and Plaintiffs refer Defendants to the Response to Interrogatory No. 15.

This skepticism is reflected even in the references cited in Defendants' response. Thus, for example, Mohs et al., *Intravenous and Oral Physostigmine in Alzheimer's Disease*, INTERDISCIPL. TOPICS. GERONT. 20: 140-52 (1985) observes that "there are no pharmacologic agents that have convincingly been demonstrated to be

effective in treating patients with Alzheimer's disease (AD)." And tellingly, that reference was published too late to qualify as prior art. And the many references cited in Defendants' response concerning the cholinesterase properties of galantamine also refute Defendants' contentions, as not one of those references even hints at the possible use of galantamine to treat Alzheimer's. Obviousness is also refuted by the many objective considerations of non-obviousness, all of which convincingly show that the use of galantamine to treat Alzheimer's as claimed in Claims 1 and 4 of the '318 patent was not obvious.

With regard to Defendants' asserted section 112, ¶ 1 defense, Defendants' assertion that the '318 patent is not enabling is contradicted by Defendants' own allegations of obviousness under section 103. The specification of the '318 patent teaches one of skill in the art to make and use the invention, and the practical utility of galantamine as a treatment for Alzheimer's was confirmed both by the animal studies described in the patent ('318 patent, col. 2, lns. 45-57), *see, e.g.*, Sweeney et al., *A Long-Acting Cholinesterase Inhibitor Reverses Spatial Memory Deficits in Mice*, PHARMACOLOGY BIOCHEMISTRY & BEHAVIOR 31: 141-47 (1988), and ultimately in human clinical trials reviewed by FDA. In addition, the manner of making and using the dosing regimens claimed in Claims 1 and 4 of the patent are similarly enabled by the disclosure of the '318 patent, including the practice of titrating to a safe and effective dose, *e.g.* '318 patent, col. 1, lns. 64-66.

Interrogatory No. 11

Identify each person that Plaintiffs have consulted or plan to consult as an expert or consultant in this action, and for each such person describe: (a) the subject matter on which the expert or consultant is expected to provide an opinion or advice; (b) the substance of the opinion(s) to be provided or advice to be rendered; (c) the factual bases for such opinion(s) or advice; (d) the documents, data or other information relied upon or considered by the expert or consultant in rendering such opinion(s) or advice; (e) the expert's or consultant's educational and professional experience; (f) the documents provided to and/or prepared by the expert or consultant, including drafts; and (g) the compensation, if any, being paid to the expert or consultant for his or her services.

Response:

In addition to the foregoing General Objections, Plaintiffs object to this interrogatory as premature in calling for the identification of persons that Plaintiffs "have consulted or plan to consult as an expert or consultant in this action." Plaintiffs also object to this interrogatory as improperly intruding into matters covered by the attorney-client privilege and work product doctrine. Plaintiffs will make timely and adequate disclosures under Rule 26(a)(2) and the Court's Revised Scheduling Order of January 12, 2006.

Interrogatory No. 12

Identify each person, whether employees of Plaintiffs or third parties involved in the evaluation, consideration, or discussion at or by Plaintiffs to develop Plaintiffs' Reminyl® / Razadyne® drug product covered by Plaintiffs NDA No. 21-169 and for each such person describe: (a) the responsibilities of that person and (b) that person's involvement in such evaluation, consideration, or discussion.

Response:

In addition to the foregoing General Objections, Plaintiffs object on the ground that identifying "each person, whether employees of Plaintiffs or third parties involved in the evaluation, consideration, or discussion at or by Plaintiffs to develop Plaintiffs' Reminyl® / Razadyne® drug product" would be unduly burdensome. Insofar

as the interrogatory seeks information concerning third parties, Plaintiffs further object that the interrogatory calls for information outside the knowledge and control of Plaintiffs. Subject to and without waiving any objections, Plaintiffs identify the following individuals:

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Interrogatory No. 13

Identify each person, whether employees of Plaintiffs or third parties, involved in the creation or submission of Plaintiffs NDA No. 21-169 or the corresponding IND, and for each such person describe their respective roles.

Response:

In addition to the foregoing General Objections, Plaintiffs object on the ground that identifying "each person" involved in the regulatory submissions identified in the interrogatory would be unduly burdensome. Subject to this objection, Plaintiffs identify Luc Truyen as an employee involved in the creation or submission of Plaintiffs' NDA No. 21-169 or the corresponding IND. For the names of additional persons involved in the NDA and IND submissions that are the subject of this interrogatory,

Plaintiffs refer Defendants to certain regulatory submissions produced in this litigation which bear the Bates numbers JAN RAZ 12667-42967 and JAN RAZ 163956-174471.

Interrogatory No. 14

Identify each instance where P.A. Bhasker, *Medical Management of Dementia*, THE ANTISEPTIC, 71(1): 45-47 (1974) was identified, evaluated, considered, or discussed by any person, whether employees of Plaintiffs or third parties in connection with the decision to file the patent application or the prosecution of the patent application that resulted in the '318 patent, and for each instance identify the person(s) involved; that person's involvement in such identification, evaluation, consideration, or discussion; and the substance of such identification, evaluation, consideration, or discussion.

Response:

The article referenced in this interrogatory, P.A. Bhasker, *Medical Management of Dementia*, THE ANTISEPTIC, 71(1): 45-47 (1974), was not identified, evaluated, considered, or discussed by any person, whether employees of Plaintiffs or third parties, in connection with the decision to file the patent application or the prosecution of the patent application that resulted in the '318 patent.

Interrogatory No. 15

Describe Plaintiffs' contentions regarding the applicability of each of the secondary considerations of non-obviousness as articulated by the Court of Appeals for the Federal Circuit, including but not limited to unexpected results, commercial success, failure of others, long-felt need, copying, skepticism in the art, licensing, and third party praise, to Defendants' allegation of invalidity of the '318 patent, and identify all documents bearing on such secondary considerations and the five (5) most knowledgeable persons concerning Plaintiffs' contentions.

Response:

In addition to the foregoing General Objections, Plaintiffs object that the interrogatory prematurely calls for information within the scope of expert discovery, and Plaintiffs reserve their rights to supplement and enlarge their positions and contentions concerning the subject matter of this interrogatory in the course of expert disclosure and

testimony. Plaintiffs also object that discovery is ongoing, and that despite repeated requests Defendants have failed to produce documents relevant to the objective considerations of nonobviousness, including licensing and failure of others. Plaintiffs accordingly reserve their right to supplement their response to this interrogatory.

Without waiving the foregoing objections, Plaintiffs contend that the validity of the '318 patent is supported by, among other things, objective considerations of nonobviousness, including without limitation: long felt need, failure of others, skepticism, recognition in the industry including licensing, copying, and acquiescence, and unexpected results.

Before the 1960s, senility was seen as a normal part of aging, and the term Alzheimer's Disease was typically reserved for the rare, presenile onset dementia. However, following the landmark British cliniconeuropathologic correlation studies in the 1960s, the epidemiology of the disease was redefined and Senile Dementia of the Alzheimer's Type was recognized as epidemic. It was also recognized that the epidemic, and its impact on society, was growing dramatically as the population aged and that there were no effective treatments for the cognitive decline that is the core feature of Alzheimer's Disease (used herein to encompass both presenile onset Alzheimer's and Senile Dementia of the Alzheimer's Type). The long felt need for such a treatment dates back at least to that time, evidence by a rapidly expanding focus on Alzheimer's research and the search for treatments, including the establishment of the National Institute on Aging, formation of the Alzheimer's Disease and Related Disorders Association (now the Alzheimer's Association), and the Alzheimer's Disease Research Centers. Yet despite a long felt need for an effective treatment for the cognitive decline associated with

Alzheimer's Disease, no such treatment had been found by January 1986, when Dr. Bonnie Davis filed the patent application that ultimately was issued as the '318 patent.

The lack of a treatment did not come from lack of trying. To the contrary, many routes to a treatment, and many possible treatments, had been tried without success. Indeed, those failures continued up to the date Razadyne® – the commercial embodiment of the '318 patent – was approved by FDA. Those failures include:

- tofranil
- prozac and other serotonin reuptake inhibitors
- guanfacine
- yohimbine
- selegiline
- rasagiline
- chelation therapy (therapy to remove aluminum from patient and blood and tissue)
- gingko biloba
- prednisone
- estrogen therapy and estradiol
- papaverine
- cyclandalate
- isoxsuprine
- ergaloid mesylates
- piracetam
- choline
- lecithin
- xanomeline
- arecoline
- bethanechol
- physostigmine
- alaproclate
- citalopram
- trazdone
- pentoxyfyllin
- nafronyl
- sabeluzole
- ACTH (and other neuropeptides)

Not surprising given the number of failures, there was considerable skepticism of pharmacologic treatments for Alzheimer's Disease. Thus, for example,

Leo Hollister of Stanford University wrote in 1985 that "[t]reatment of [Alzheimer's Disease] is presently far from satisfactory. Many physicians have taken such a negative view of the prospects that they refuse to try anything." L.E. Hollister, *Survey of Treatment Attempts in Senile Dementia of the Alzheimer Type*, in C.G. Gottfries, ed., NORMAL AGING, ALZHEIMER'S DISEASE AND SENILE DEMENTIA: ASPECTS ON ETIOLOGY, PATHOGENESIS, DIAGNOSIS AND TREATMENT 299-306 (Editions de l'Université de Bruxelles: 1985). Professor Hollister's article also provides a survey of treatment strategies at the time, all of which save the cholinesterase inhibitors have failed.

In addition to this general skepticism, there was also considerable skepticism in the art concerning treatment strategies focused on the cholinergic system, which galantamine as a cholinesterase inhibitor is. By the date of application, Alzheimer's Disease was known to be associated with a wide variety of neurologic disorders and neurochemical deficiencies, including for example, acetylcholine, norepinephrin, serotonin, somatostatin, vasopressin, and β-endorphin. Many believed that a therapeutic strategy focused on a single neurotransmitter was doomed to fail, a belief strengthened by the failure of choline precursor therapy. Instead, the range of disorders and deficits associated with Alzheimer's Disease encouraged many to pursue (fruitlessly, as it turned out) drugs that were thought to provide broader neuroprotective or cognition enhancing properties, such as the so-called "nootropics."

What is more, there were many who were particularly skeptical about the possibility of developing a successful treatment for Alzheimer's Disease using a cholinesterase inhibitor. As indicated above, the perceived breadth of the disorder and degradation of the cholinergic system made many skeptical that a cholinergic approach,

including use of a cholinesterase inhibitor, would afford any therapeutic benefit. In addition, there were concerns that cholinesterase inhibitors would have too small a therapeutic index – exacerbated by the frail nature of typical Alzheimer's patients, would lack specificity, and would impair the phasic nature of synaptic firing. Concern was expressed that cholinesterase inhibitors might in fact promote degradation of the cholinergic system, either through cholinesterase up-regulation or through depletion of free choline at nerve terminals and consequent acceleration of the hydrolysis of membrane phospholipids.

Skepticism of cholinesterase inhibitors was expressed both at the time of application and later,

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Others include: Mitsui Pharmaceuticals, Inc., which decided not to develop a galantamine product because it perceived a poor correlation between animal data and clinical efficacy in patients with Alzheimer's Disease and its fear of unexpected adverse effects in patients during long-term treatment (SYN RAZ-0000594-595); Boehringer Ingelheim KG, which asserted that galantamine did "not have the biochemical and pharmacological profile which [Boehringer] consider[ed] essential for [galantamine's] potential use in the treatment of Alzheimer's disease" (SYN RAZ-0001076; SYN RAZ-0000270); E.R. Squibb & Sons, which expressed concern that

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the Upjohn Company, which stated that it was "already fully committed to other mechanistic approaches to Alzheimer's Disease which [Upjohn] consider[ed] more promising than that offered by galantamine" (SYN RAZ-0017576).

Moreover, even for those interested in developing an Alzheimer's treatment using a cholinesterase inhibitor, many failed. Failed cholinesterase inhibitors include:

- metrifonate
- huperzine
- physostigmine and physostigmine SR
- hyptylphysostimgine
- pyridostigmine
- edrophonium
- sypnapton
- SM 1088
- zifrosilone
- amiridin
- velnacrine
- phenserine
- ganstigmine
- quilostigmine
- suronacrine
- TAK 147
- epistigmine
- methanesulfonyl fluoride
- CP 118,954
- KA 672
- Gen 2819

In addition, Razadyne® – the commercial embodiment of the '318 patent – has been a tremendous commercial success, whether measured by prescriptions, total sales, or overall profitability. The success of Razadyne® is shown by the marketing and commercial documents that have been and will be produced by Plaintiffs, as well as by Defendants' own sales projections and marketing studies (in addition to their

individual decisions to develop and seek approval for generic copies of the Razadyne® product).

The validity of the '318 patent has been recognized in the industry, both through licensing, copying, and acquiescence of others. As for licensing, both Ciba Geigy (now Novartis) and Janssen licensed the '318 patent in order to develop a galantamine drug product for treatment of Alzheimer's Disease in the United States. In addition, since Razadyne® was approved, 17 pharmaceutical companies that have filed ANDAs seeking to market generic copies of Razadyne®. Ten of these companies have further acquiesced in the validity of the '318 patent, certifying to FDA that they will not seek approval to market their generic copies until after that patent expires. They are Apotex Inc. (ANDA No. 77-781); Cobalt Pharmaceuticals, Inc. (ANDA No. 77-823); Eon Labs Manufacturing, Inc. (ANDA No. 77-607); IVAX Pharmaceuticals, Inc. (ANDA No. 77-609); Mutual Pharmaceuticals Co. (ANDA No. 77-586); Ranbaxy Laboratories Ltd. (ANDA No. 77-588); Roxane Laboratories, Inc. (ANDA No.77-608); Sandoz Inc. (ANDA No. 77-589); Sun Pharmaceutical Industries, Ltd. (ANDA No. 77-592); and Watson Laboratories, Inc. (ANDA No. 77-767).

Finally, galantamine has proven to have many unexpected and surprising benefits from the perspective of one of skill in the art at the time of filing the application. In addition to the cognitive benefits provided by galantamine, the drug also reduces the neuropsychiatric disorders associated with Alzheimer's Disease, such as agitation and depression. Galantamine has been found to improve the activities of daily living of Alzheimer's patients and also to lighten the burden on caregivers. Evidence also suggests that galantamine delays nursing home placement. And it is the only cholinesterase

inhibitor shown in an FDA-reviewed pivotal trial to be effective in all four major trial outcomes – global, cognitive, functional, and behavioral.

In addition, galantamine has unexpectedly been discovered to promote cholinergic function not only through inhibition of cholinesterase, but also through allosteric modulation of the nicotinic receptor. This second mechanism of action for galantamine distinguishes it from all the other cholinesterase inhibitors and may well play an important role in promoting cognitive function and possibly slowing progression of Alzheimer's Disease.

In addition to experts who will be identified pursuant to Rule 26(a)(2) and the Court's Revised Scheduling Order of January 12, 2006 and the individuals identified in Plaintiffs' Rule 26(a)(1) initial and supplemental disclosures, Plaintiffs refer Defendants to the individuals identified in response to Interrogatory No. 12.

Interrogatory No. 16

Describe the facts and circumstances regarding any licensing discussions and any actual or considered litigation between Plaintiffs and Waldheim Pharmazeutika GmbH regarding any United States or foreign patent(s) for the use of galantamine for the treatment of Alzheimer's disease or related dementia, including but not limited to any arguments set forth by Waldheim Pharmazeutika GmbH regarding any asserted invalidity of such patent(s), any actual or proposed settlement agreements, and any litigation outcomes, and identify all related documents and the five (5) most knowledgeable persons including that person's involvement, concerning the facts and circumstances.

Response:

In addition to the foregoing General Objections, Plaintiffs object to this interrogatory as intruding on matters covered by the attorney-client privilege and work product doctrine. Plaintiffs further object to this interrogatory because it seeks information that is irrelevant and immaterial to the matters involved in this action and is

not reasonably calculated to lead to the discovery of evidence that would be admissible herein. To the extent any non-privileged information exists concerning the subject matter of this interrogatory, and subject to Plaintiffs' relevance objection,

REDACTED

ASHBY & GEDDES

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John G. Day (I.D. # 2403)
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Dated: May 22, 2006
169716.1

CERTIFICATE OF SERVICE

I hereby certify that on the 22nd day of May, 2006, the attached **PLAINTIFFS JANSSEN PHARMACEUTICA N.V.'S, JANSSEN, L.P.'S, AND SYNAPTECH, INC.'S OBJECTIONS AND RESPONSE TO DEFENDANTS TEVA PHARMACEUTICALS, USA, INC.'S AND TEVA PHARMACEUTICAL INDUSTRIES LTD'S SECOND SET OF INTERROGATORIES** was served upon the below-named counsel of record at the address and in the manner indicated:

HAND DELIVERY

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Lauren E. Maguire

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE: '318 PATENT INFRINGEMENT LITIGATION	)))	C.A. No. 05-356-KAJ (consolidated)

NOTICE OF SERVICE

The undersigned hereby certifies that on the 22nd day of May, 2005, **PLAINTIFFS JANSSEN PHARMACEUTICA N.V.'S, JANSSEN, L.P.'S, AND SYNAPTECH, INC.'S OBJECTIONS AND RESPONSE TO DEFENDANTS TEVA PHARMACEUTICALS, USA, INC.'S AND TEVA PHARMACEUTICAL INDUSTRIES LTD'S SECOND SET OF INTERROGATORIES** was served upon the following counsel of record at the address and in the manner indicated:

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ASHBY & GEDDES

/s/ Lauren E. Maguire

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Tel: 732-524-2805

Dated: May 22, 2006

162677.1

CERTIFICATE OF SERVICE

I hereby certify that on the 22nd day of May, 2006, the attached **NOTICE OF SERVICE** was served upon the below-named counsel of record at the address and in the manner indicated:

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/s/ *Lauren E. Maguire*

Lauren E. Maguire

Exhibit H

KIRKLAND & ELLIS LLP
AND AFFILIATED PARTNERSHIPS

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June 12, 2006

VIA FACSIMILE

Kurt Calia, Esq.
Covington & Burling
1201 Pennsylvania Avenue, N.W.
Washington, DC 20004-2401

Re: *In re '318 Patent Litigation*, Civil Action No. 05-356 (KAJ)

Dear Kurt:

This follows-up on our telephone conference on Thursday, June 8, 2006.

1. **Teva's May 9, Notice Of Rule 30(b)(6) Deposition To Janssen and plaintiff Janssen's objections to the same.**

With respect to Topic No. 1, we understood you to agree that the plaintiffs' would present a witness to provide any non-privileged information responsive to the Topic.

With respect to at least Topics Nos. 2-4, and any other Topics that seek discovery beyond the NDA product, you explained that plaintiffs objected because the discovery sought was beyond the parties' agreement on "other products."

REDACTED

Relatedly,

REDACTED

I agree generally with Chris that a deposition examiner need not explain the relevancy basis for questions during a deposition (and I did not instruct not to answer on that basis), but I am entitled to know why the discovery sought is relevant, and I see no reference to any conceivable relevance in your interrogatory responses. Please explain why plaintiffs have elected to pursue this discovery. As you know, Teva has not pursued its discovery on the plaintiffs' pre-filing investigation -- *see* Interrogatory No. 3--in light of the

Court's decision removing willful infringement from the case. As you apparently believe discovery on attorney work product and privileged information remains relevant in the case, we are prepared to pursue it as well and your response to Interrogatory No. 3 provides none of the requested information.

With respect to Topics Nos. 3-4, you explained that plaintiffs' objected as overly broad on the grounds that no witness could be expected to know all the persons involved in the subject matter of the topic and that the parties agreed that only "high level" persons were expected to be identified, and not every person involved, including for example every lab technician. We agree as long as plaintiffs expect no more from Teva's Rule 30(b)(6) witnesses.

With respect to Topics 2-5, we understood you would produce a witness subject to the objections described above.

With respect to Topics 6 and 7, you explained the main basis for objection was privilege and that otherwise a prepared witness would be presented.

With respect to Topic No. 8, we are not sure what your position is. We explained that we expect a fully prepared witness would be presented, as Teva provided. Please clarify your position.

With respect to Topic No. 9, you indicated that plaintiffs had agreed with defendants not to pursue this topic. We were not aware of that agreement when the notice was served and are unaware of it now. We will honor any such agreement but otherwise we see no basis for plaintiffs to refuse to provide a witness on this topic.

With respect to Topic Nos. 10 and 11, we understood you would provide a witness.

With respect to Topics 12 and 13, you explained you understood there was agreement that the parties would take these topics up within the other substantive topics. We agree and understood this to be the approach taken by all parties with respect to such topics.

We received your June 9, 2006 e-mail offering a witness on this Rule 30(b)(6) notice for June 23, 2006. I am presently unavailable that day but will try to change my schedule to accommodate that requested date of deposition. I will let you know shortly.

Please provide us with the name of the witness(es) in response to the notice.

2. Plaintiffs' Responses to Teva's Second Set of Interrogatories.

With respect to Interrogatory No. 11, we agreed the parties would not provide expert discovery in advance of the schedule in the Court's scheduling order.

With respect to Interrogatory Nos. 12 and 13, you explained the objection was similar to those the defendants made as to the overbreadth of seeking all persons who may be responsive to the interrogatory. We will agree to hold plaintiffs to the same degree of specificity with which plaintiffs seek from defendants.

We disagreed as to the sufficiency of plaintiffs' responses to Interrogatory Nos. 15 and 16.

3. Plaintiffs' Responses to Teva's First Set of Interrogatories.

I inadvertently did not discuss plaintiffs' response to Interrogatory No. 9 from our first set of interrogatories. I will call you regarding the same unless you agree to supplement the interrogatory.

4. Other matters discussed.

We discussed the status of several other matters on our call.

Electronic Discovery and Expert Stipulations. As you note in your June 9 e-mail to Karen Robinson and me, we promised to get back to you on the status of the electronic discovery and expert discovery stipulations. We will do so and expect we can resolve any remaining issues quickly for all parties' benefit.

Teva's 2nd Rule 30(b)(6) Notice. I asked when plaintiffs intended to present a witness in response to Teva's second notice of Rule 30(b)(6) deposition, which is presently noticed for Tuesday, June 13, 2006. You said you would inquire with your team and get back to me. We agreed that the parties would continue to give each other adequate notice for dates and locations when depositions were going forward. In that regard, having heard nothing from plaintiffs, we obviously are not going forward with Tuesday's deposition pursuant to Teva's second notice. Please provide us with alternative dates and the name of the witness.

Plaintiffs' Nine New Third Party Depositions. I also inquired as to the status of the nine third party subpoenas plaintiffs served two weeks ago, including four with noticed depositions this Tuesday and one with a noticed deposition this Wednesday. You promised to get back to us. We need to know the status of these depositions, whether the subpoenas have been served, whether any documents were produced, whether motions for protective order or objections were filed, and, of course, when and where the deposition is scheduled to take place to preserve our rights and defend ourselves this litigation. Please keep us timely apprised of these matters.

IVAX Subpoena. With respect to the third party subpoena on IVAX, I understood us to agree that the deposition would not go forward on Tuesday, June 13, 2006 as noticed and that we would discuss a stipulation to resolve the subpoena. ***Please let us know if you disagree with my understanding and please confirm we may have an extension of time within which to file a motion for protective order should we be unable to resolve the subpoena by stipulation.***

Individuals Named In Teva Supplemental Interrogatory Response. With respect to the two Teva Ltd individuals named in our most recent interrogatory supplements directed to the issue of "individuals" who made "contributions" to the ANDA, I confirmed we did not intend to call them at trial (necessarily based on plaintiffs' contentions to date which in no way implicates any involvement they had in the ANDA) but rather to provide a more complete disclosure in response to your interrogatory.

Mr. Alain Raoult. I inquired as to whether plaintiffs intended to call Mr. Alain Raoult as a trial witness and asked if you would make him available for deposition in the United States. Mr. Raoult was recently added to plaintiffs' initial disclosures and is cited in plaintiffs' interrogatory responses. Please let me know the answer and also whether Mr. Raoult is a present employee of plaintiffs.

Please let me know you disagree with any of the above and please call me with any questions.

Sincerely,

Edward C. Donovan /kmr

Edward C. Donovan

REDACTED

Exhibit I

REDACTED

REDACTED

Exhibit J

REDACTED